

Serial No. 10/586,100 - - - - - 2 Date of Response: September 30, 2009

REMARKS

Summary of the Status of the Claims

This application originally was subjected to a restriction of invention, and the claims of the present application had been made subject to a requirement for an election of species of the generic invention. Applicants elected species is a water-dispersible, self-emulsifying fatty acid-derived conditioner which is a blend of a combination of three components, a caprylic/capric triglyceride, a glyceryl cocoate/citrate/lactate, and a PEG-40 sorbitan oleate, as is specifically claimed in claim 8, as now presented of record, which depends on claim 1; in claims 36 and 37, which depend on claim 35; and in claims 39 and 40 which depend on claim 38. Claims 1, 2, 3, 9-17, 24, 25, 28-31, 33 and 35-40 all read on the elected species.

The status of the claims is as follows: Claims 1, 3, 8-17, 24, 25, 28-31, 33, and 35-40, directed to the elected compositions, claimed elected species and articles of manufacture, are pending in this application. Claims 2, 5-7, 20, 26-27, 32 and 34 have been canceled without prejudice. The non-elected species claim 4 and non-elected method claims 18, 19 and 21-23 are withdrawn.

Summary of the Claimed Subject Matter

The present claims are directed to a substantially anhydrous, free-flowing granular composition containing a water-dispersible, self-emulsifying, fatty acid-derived conditioner blend defined by the combination of materials and specific claimed elected species recited in the claims. The claimed conditioner blend is a combination of non-aqueous ingredients referred to in the specification as the "SFC" portion of the formulation in Table 1 and Table 2, for example, and which is physically admixed with the dry ingredients of the powder portion of the resulting free-flowing granular composition. (See Examples 1, 2, 8, 9 and 10).

Addressing the Examiner's remarks concerning the transitional phrases in Applicants' claims, Applicants have clearly indicated in the specification and claims the basic and novel water dispersible, self-emulsifying characteristics of the claimed fatty acid-derived conditioner blend and of Applicants' granular composition when it is later mixed with an aqueous

Serial No. 10/586,100----- 3 Date of Response: September 30, 2009

medium. The granular composition surprisingly immediately forms a conditioning hair lightener emulsion (i.e., within 5 minutes as defined in paragraph [0043] of the Pre-Grant published application US2008/0229512) with minimal manual mixing agitation (see paragraph [0043] of the published application). These basic and novel characteristics of the Applicants' claimed conditioner blend, elected species and composition are not shown in the prior art.

The transitional phrase of "consisting essentially of" in Applicants' claim 1 and claims dependent therefrom, therefore, excludes components that would materially affect the water-dispersible, self-emulsifying characteristics of the Applicants' fatty acid-derived conditioner blend in accordance with the requirements set forth in MPEP §2111.03. The basic and novel characteristics of Applicants' claimed conditioner blend and species are not shown in the cited prior art.

The transitional phrase of "consisting of" in Applicants' claims 35-40 likewise defines the basic and novel water-dispersible, self-emulsifying characteristics of Applicants' fatty acid-derived conditioner blend. Hence, Applicants' claims would exclude from the granular composition even a de-dusting agent if it materially affected the immediate formation of a conditioning hair lightener emulsion, when the granular composition was later admixed with an aqueous medium. Further, as established herein, the basic and novel characteristics of Applicants' claimed specific conditioner blend and elected species and the surprising immediate formation of an emulsion when Applicants' granular composition is admixed with an aqueous medium, are not shown in the prior art. Therefore, claimed features, such as concentration and temperature, in Applicants' claims are not, and cannot be, merely optimization through routine experimentation of prior art disclosures.

The prior art does not teach (1) Applicants' specific elected conditioner blend for concurrently conditioning hair during a hair bleaching procedure or (2) that Applicants' specific combination blend of the separately known fatty acid-derived materials is self-emulsifying when the granular composition is later admixed immediately before use with an aqueous medium; or (3) that Applicants' water-dispersible, self-emulsifying fatty acid conditioner blend forms a conditioning hair lightener emulsion surprisingly substantially immediately when the granular composition is later admixed with an aqueous medium.

Serial No. 10/586,100 ----- 4

Date of Response: September 30, 2009

Here, Applicants have also presented data showing that the resulting so-formed hair lightener emulsion also surprisingly beneficially ameliorates one or more deleterious effect on the tensile and tactile properties of hair oxidatively lightened under relatively high alkaline conditions, even when no hair protectant, deswelling agent is present (See Examples 5-7). In assessing an obviousness rejection, *all* of the evidence must be considered. Data in the specification that shows an unexpected and substantial improvement over the prior art suffices to show unexpected results, in the absence of evidence to the contrary. *In re Soni*, 34 USPQ2d 1684, 1688 (Fed. Cir. 1995).

The subject matter of Applicants' claims is patentable over the prior art and all the art-based rejections should be withdrawn as discussed below.

The Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3, 8, 9 and 35-40 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Schultz *et al.* (U.S. Patent 5,866,107) in view of Cincotta *et al.* (Pre-Grant Publication US2002/0155962). Applicants traverse this rejection.

The Office Action correctly admits that: "The difference between the teachings of Schultz *et al.* and the instant claims is that Schultz *et al.* does not teach the claimed species of conditioners." but then incorrectly asserts that: "This deficiency in Schultz *et al.* is cured by the teachings [sic] Cincotta *et al.*" Applicants submit that the references do not make the present invention as a whole obvious.

In supporting the rejection, the Examiner's primary reasons are:

"Cincotta *et al.* teach, as a whole, a non-aqueous (hence substantially anhydrous) composition to style hair which contains many optional hair conditioners (fixatives, humectants, emollients, etc.)...".

Cincotta *et al.* teach a vast number of hair conditioners (as emollients) which may be included in combination in a hair active composition (paragraph 47). ...".

concluding that: "The skilled artisan would have been motivated to incorporate the claimed conditioners because Schultz *et al.* teaches the inclusion of hair conditioners in the composition and Cincotta *et al.* teaches that the specifically claimed species are suitable as hair conditioners."... and asserting that: "Reading a list and selecting a known compound to meet

Serial No. 10/586,100 ----- 5 Date of Response: September 30, 2009

known requirements is no more ingenious than selecting the last piece to put in the last opening a jig-saw puzzle." [citation omitted, emphasis added].

The teachings of Cincotta *et al.*, however, do not cure the deficiency in Schultz *et al.* Cincotta *et al.* would not motivate, or even enable, the skilled artisan to select Applicants' specific combination of materials to obtain Applicants' water-dispersible self-emulsifying fatty acid-derived conditioner blend. In making the obviousness determination, the Examiner ignores the number of variables that would need to be considered and modified in the prior art to arrive at Applicants' present invention. See MPEP 2144.08(a)(c). This is not a case of simply "reading" a listing of compounds as asserted by the Examiner.

Paragraph 47 (starting on page 6 through page 9) of the Cincotta *et al.* reference, on which the Examiner relies, is a 5-column listing of a staggering number of individual diverse emollients. Conservatively estimated, the number of individual compounds listed is at least 1,000 which would result in a practically infinite genus of mixtures containing two or more of the listed materials. Even if only a combination of three compounds were selected, the number of potential combinations of three compounds would be in the millions; i.e., 1,000 factorial divided by (3 factorial X 997 factorial) =166,167,000.

A disclosure of millions of compounds cannot render a claim obvious. *In re Baird*, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (in reversing the Examiner, the Court stated: "In the instant case, the generic diphenol formula disclosed in Knapp contains a large number of variables, and we estimate that it encompasses more than 100 million different diphenols, only one of which is bisphenol A. While the Knapp formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables..."). As shown above, the number of potential combinations of three materials from the vast list in Cincotta *et al.* is well over 100 million. If the members of a species cannot be envisioned from a broad genus, the reference does not disclose the species and the reference is not enabling. *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 81 USPQ2d 1001 (Fed. Cir. 2006), citing *In re Petering and Fall*, 133 USPQ 275, 281 (CCPA 1962) (nothing in the patent would lead one of ordinary skill in this art to select and prepare the

Serial No. 10/586,100 ----- 6 Date of Response: September 30, 2009

particular compounds from a broad generic class even if the claimed compounds are encompassed by the broad generic class). Cincotta *et al.* is not an enabling reference.

Here, the Examiner is, in effect, erroneously taking the position that it would be obvious to try each of the numerous individual compounds listed by Cincotta *et al.* However, the claims require a blend defined by the claimed combination of three materials, not individual compounds. This is clearly not a case where only a "finite number" of materials are available which would be obvious to try, nor does Cincotta *et al.* provide any direction as to which of many possible choices is likely to be successful. (See MPEP 2145 X(B)). Even if one of ordinary skill in the art might find it obvious to try various combinations of conditioners, that is not the standard of 35 U.S.C. §103(a).

Recently, the Federal Circuit admonished against the erroneous application of an obvious to try standard in *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 91 USPQ2d 1569 (Fed. Cir. 2009) stating:

First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When 'what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful' an invention would not have been obvious. [quoting *In re O'Farrell*, 7 USPQ2d 1673,1681 (Fed. Cir. 1988)]. *Id.* at 1681.

That Cincotta *et al.* list a vast number of individual compounds, some of which can be combined resulting in an impractical number of potential combinations, provides no teaching, suggestion or direction leading one of ordinary skill in the art to select only the specific combination of three members set forth in Applicants' claims to the exclusion of the vast number of other possible combinations. Nothing in Cincotta *et al.* teaches or suggests a combination of ingredients that provides a water-dispersible conditioner blend and species when the combination is mixed with an aqueous medium. Nothing in Cincotta *et al.* teaches or suggests that a combination of ingredients that provides a self-emulsifying conditioner blend and species when

Serial No. 10/586,100 - - - - - 7

Date of Response: September 30, 2009

the granular composition containing the claimed combination is mixed with an aqueous medium. In short, nothing in Cincotta *et al.* teaches, suggests, or provides direction for, the selection of a combination of ingredients in Applicants' claimed combination of water-dispersible, self-emulsifying fatty acid-derived conditioner blend and species. At best, Cincotta *et al.* provides a general invitation to experiment with myriad combinations of conditioners, nothing more.

To be sure, "to have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *Pfizer v. Apotex*, 480 F.3d 1348, 82 USPQ2d 1321, 1333 (Fed. Cir. 2007), cert. denied, 128 S.Ct. 110 (2007), quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (internal quotations omitted). See also *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) which reversed the Board's rejection, reasoning that the prior art reference encompassed a "potentially infinite genus" of salts of dicamba and listed several such salts, but that it did not disclose or suggest the claimed salt. Here, Cincotta *et al.* do not specifically disclose the claimed blended combination of three materials. Moreover, those skilled in the hair treatment art area recognize that hair conditioning results, whether objective or subjective, obtained from combining conditioner compounds is not a predictable science given the complex nature of hair.

A *prima facie* case for obviousness requires that the asserted combination of references teaches or suggests all of the limitations of the rejected claims. *In re Royka*, 180 USPQ 580, 583 (CCPA 1974). There must be some teaching, suggestion, or incentive supporting the combination. *In re Geiger*, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987) (no *prima facie* case of obviousness presented since none of the references suggested the claimed combination).

Applicants respectfully submit there is no rationale or motivation found in Schultz *et al.* and Cincotta *et al.* alone or in combination, for a skilled artisan to incorporate the claimed combination of conditioners into the composition of Schultz *et al.* as proposed by the Examiner. There is no teaching or suggestion in Schultz *et al.* of forming any emulsion at all when the powder bleach is mixed with hydrogen peroxide. Therefore, there is no motivation in Schultz *et al.*

Serial No. 10/586,100 ----- 8 Date of Response: September 30, 2009

al. that would lead one of ordinary skill in the art to seek, select, and blend a combination of ingredients that provide a water-dispersible, self-emulsifying conditioner or for immediately forming an emulsion when the powder bleach is mixed with hydrogen peroxide. It is well known that a reference that merely indicates that isolated elements or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. *Ex Parte Hiyamizu*, 10 USPQ2d 1393, 1394-95 (BPAI 1988). Schultz *et al.* do not provide any teaching or suggestion that would motivate a person skilled in the art to select and combine specific conditioners to arrive at Applicants' invention and claimed species.

Neither would one of ordinary skill in the art have been motivated to look to, or even be enabled by, the Cincotta *et al.* reference to arrive at the specific combination of materials constituting Applicant's claimed species of water-dispersible, fatty-acid derived conditioner blend. There is no teaching or suggestion in Cincotta *et al.* of granular powder compositions of any kind, or of concurrently conditioning the hair during any aqueous chemically reactive (i.e., hair active) treatment, e.g., bleaching, or of admixing the Cincotta *et al.* composition with any aqueous medium at all. Cincotta *et al.* focus only on non-aqueous, liquid, hair styling compositions to overcome the negative problems associated hair styling using aqueous hair styling compositions (see paragraph [0015] of the Pre-Grant published application US2002/0155962). Therefore, Cincotta *et al.* clearly teach away from using any aqueous compositions, because to do so would negate the hair styling purpose of Cincotta *et al.* Hence, there is no teaching, suggestion or motivation to admix the composition of Cincotta *et al.* with an aqueous medium at all as taught by Schultz *et al.*

Persons skilled in the hair styling and chemical hair treatment arts understand that bleaching and styling of hair are discreetly different treatments. Hair bleaching requires an aqueous composition for effectiveness, whereas holding the properties of a hair style is negatively affected by aqueous mediums. Here common sense would lead away from combining these treatments into a single composition. Thus, there is no motivation for a person skilled in the hair bleaching art to look to Cincotta *et al.* for guidance.

Serial No. 10/586,100 ----- 9 Date of Response: September 30, 2009

It is well established that each prior art reference must be evaluated in its entirety and that all of the prior art must be evaluated as a whole. As stated by the CCPA: "It is impermissible to first ascertain factually what appellants *did* and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants' invention." [emphasis in original] *In re Shuman*, 150 USPQ 54,57 (CCPA 1996) quoted in *Panduit Corp. v. Dennison Manufacturing Co.*, 227 USPQ 337, 342-43 (Fed. Cir. 1985). The proper approach to the obviousness issue must start with the claimed invention as a whole. It is immaterial to the issue that some or all aspects of the claim may have been otherwise known in the art. *Jones v. Hardy*, 220 USPQ 1021, 1024 (Fed. Cir. 1984). What must be found obvious is the claimed combination. *Kimberly-Clark Corp. v. Johnson & Johnson*, 223 USPQ 603, 609-10 (Fed. Cir. 1984).

The Examiner admits that the prior art does not teach Applicants' conditioner combination blend. Indeed, the Examiner does not, and cannot, point to anything in the prior art that teaches the combination of the three specific components of Applicants' claimed elected species in claims 8, 36, 37, 39 and 40.

The Examiner has failed to make a proper *prima facie* case in support of the asserted ground for rejection. The art-based rejection of Claims 1, 3, 8, 9 and 35-40, as presented of record, must be withdrawn.

Claims 10-17, 24, 25, 28-31, and 33 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Schultz *et al.* and Cincotta *et al.* as applied to claim 1 above, and further in view of Syed *et al.* (U.S. Patent 5,756,077). Applicants traverse this rejection.

The Examiner admits that: "The difference between the teachings of Schultz *et al.*, and Cincotta *et al.* and the instant claims is that Schultz *et al.*, and Cincotta *et al.* do not teach adding the specifically claimed hair protectants." Applicants disagree, however, with the Examiner's assertion that: "This deficiency in Schultz *et al.* and Cincotta *et al.* is cured by the teachings of Syed, *et al.*"

The failure of the primary Schultz, *et al.* reference, and the secondary Cincotta *et al.* reference, individually or in combination with one another, to make obvious Applicants' present invention as a whole and the specific claimed species, in particular, was discussed in

Serial No. 10/586,100 ----- 10 Date of Response: September 30, 2009

detail above and is repeated herein by reference. Additionally, while the Examiner correctly states that: "Syed, et al., teach, as a whole, a method for protecting chemically treated hair and a kit for using the compositions to protect hair.", Syed *et al.* do not teach or suggest free-flowing, granular compositions of any kind. The compositions of Syed *et al.* are aqueous liquids that are applied to previously damaged hair to protect the previously damaged hair by blocking the action of subsequent treatment with the same chemical treatment. Thus, Syed *et al.* do not teach or suggest conditioning hair concurrently with bleaching.

In Applicants' claimed granular composition, the hair protectant ingredient is an optional, auxiliary ingredient, whereas it is an essential ingredient in the composition of Syed *et al.* In contrast to Syed *et al.*, when a hair protectant is present in Applicants' claimed composition, it is concurrently present during the subsequent chemical treatment (i.e., bleaching). There is no teaching, or suggestion, or motivation in Syed *et al.* to prepare a free-flowing, granular composition or Applicants' claimed species combination of water dispersible, self-emulsifying fatty-acid derived conditioners. Thus that Syed *et al.* teach the selective individual components cited by the Examiner, does not render the Applicants' claimed invention as a whole obvious either alone, or in combination with, the primary and secondary reference.

In assessing the differences between the prior art and the claimed invention, the Federal Circuit stated in *Ruiz v. A.B. Chance Company*, 69 USPQ2d 1686 (Fed. Cir. 2004):

In making the assessment of differences, section 103 specifically requires consideration of the claimed invention 'as a whole.' Inventions typically are new combinations of existing principles or features... The 'as a whole' instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference

Serial No. 10/586,100 ----- 11 Date of Response: September 30, 2009

containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components would discount the value of combining various existing features or principles in a new way to achieve a new result -- often the very definition of invention.

Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. *Id* at 1690.

See also MPEP 2141.02 (I) which states: "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratosflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)...").

For reasons discussed in detail above, in the absence of Applicants' teachings, there is no teaching, suggestion, motivation or direction in the prior art that would lead to Applicants' claimed invention as a whole, and elected species in particular. Even common sense would lead a skilled artisan away from combining the art as proposed by the Examiner. Applicants submit that the obviousness rejection is based on impermissibly breaking the invention and the elected species into its component parts from isolated disclosures in the prior art and reconstructing Applicants' invention through hindsight.

Hindsight reconstruction may not be used to pick and choose from among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). See also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007) (a fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasonings, citing *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966).

Serial No. 10/586,100 - - - - - 12 Date of Response: September 30, 2009

The Examiner's motivation to combine the asserted art and the asserted rationale for this rejection, therefore, could only have come from an improper use of hindsight to construct the claimed invention. This rejection of Claims 10-17, 24, 25, 28-31 and 33, as presented of record, must be withdrawn.

CONCLUSION

Applicants submit that none of the cited prior art teaches, suggests, or provides motivation or direction for selecting Applicants' materials for the claimed conditioner combination blend of specific water-dispersible, self-emulsifying, fatty-acid derived conditioners, or the specific blend of three materials in the elected species, or the basic and novel characteristics of Applicants' substantially anhydrous, free-flowing granular composition as set forth in the claims. Claims 1, 3, 8-17, 24-25, 28-31, 33 and 35-40 as presented of record are believed to be in condition for allowance. Reconsideration and withdrawal of all the art-based rejections is requested.

Applicants respectfully request allowance of all of the claims, and early passage of the application to issue. In the event the finality of the present Office Action is maintained, however, Applicants request entry of this Response into the record for placing the record in condition for Appeal.

Respectfully submitted,

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